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K030730

dbc - DIAGNOSTICS BIOCHEM CANADA INC.
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DATE: July 2, 2003

Contact Person: Dr. G. R. Dumont
Tel (519) 681-8731

19. 510 K Summary

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

1. The assigned 510K number is K030730

2. The classification name of the device: Enzyme immunoassay for free testosterone

3. Classification number 862.1680

4. Proprietary name: Free Testosterone by Enzymeimmunoassay (EiA) Class I

5. Use of the device: Direct determination of Free Testosterone by enzymeimmunoassay (Elisa) in human serum. It is an in-vitro diagnostic kit

6. The predicate device's name and address of which we claim equivalence: Diagnostics Products Corporation, (DPC), 5700 West 96 Street, Los Angeles, CA, 900159597

COAT-A-Count' Free Testosterone kit
Cat. No. TKTF1 (100 tubes) and TKFT2 (200 tubes)
510(K) K844423

7. The free Testosterone Elisa kit consists of one polyclonal antibody which is coated on microtiter plate (96 wells per kit). The antigen Testosterone 3 carboxymethyl oxime

is conjugated to an enzyme namely horse radish peroxidase. The standards are prepared in human serum matrix and all other reagents within the kit namely assay buffer, wash buffer concentrate, substrate tetramethytbenzidine (TMB) and stopping solution. 50 ul of patient serum , control serum and each standard are added to each well. 100 ul of conjugate solution is again added to each well. The incubation time is 37°C for 60 minutes. After incubation the plates are washed 3 times, each time with 300 ul of diluted wash buffer. The plates are dried. 100 ul of substrate TMB is added to each well and allowed to incubate for 10 - 15 minutes at 37°C. 50 ul of stopping solution is added into each well and the colour becomes yellow. The plate is read within 20 minutes in a microtiter plate reader at 450 nm.

8. Substantial equivalence:

1. The DBC In-vitro diagnostic device namely free Testosterone by enzymeimmunoassay (EiA) has the same intended use as current device on the market referred to "predicate device".

2. The dbc In-vitro diagnostic device namely free Testosterone has the same characteristics as predicate device namely antigen/antibody.

3. The dbc results obtained of a number of human serum samples substantial equivalent to the predicate device. The results need not be exactly the same but a correlation of equivalence is necessary in this case r=0.8908

4. The dbc free testosterone reflect the same equivalence as the predicate devices which can be found in our results of performance characteristics namely; sensitivity, specificity, Intra and Inter assay precision and the results of 61 human serumsamples

5. dbc free testosterone intended use, methodology, reagents materials and control serum necessary to perform the test are similar to the predicate device.

6. Our 510K presentation demonstrates substantial equivalence to predicate device in regards:

- intended use
- performance
- material
- effectiveness
- standards
- control

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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G.R. Dumont, M.D., M.Sc.
Director of Laboratories
Diagnostics Biochem Canada, Inc.
1020 Hargrieve Road
London, Ontario
CANADA N6E 1P5

Re: k030730
Trade/Device Name: EiAsy™ Free Testosterone EiA
Regulation Number: 21 CFR 862.1680
Regulation Name: Testosterone test system
Regulatory Class: Class I
Product Code: CDZ
Dated: May 28, 2003
Received: May 29, 2003

Dear Dr. Dumont:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

18. Statements of Indication for Use

510K number K030730

Device Name: EiAsy™ Free Testosterone EiA

Indication for Use:

The dbc CAN-fTE-260 EiAsy™ Free Testosterone enzymeimmunoassay (EiA) kit provides the reagents necessary for the direct determination of Free Testosterone in human serum. This assay is intended for in vitro diagnostic use only. Measurement of Free Testosterone are used in the diagnosis in male sex hormones (androgens) and in females hirsutism (excessive hair) and virilisation (masculinization).

Prescription USE.....X..... **Or** **Over-The-Counter Use.....**

(Per 21 CFR 801.109

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K030730